#### ZYRTEC ALLERGY- cetirizine hydrochloride tablet, film coated Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division

Zyrtec® Allergy

**Drug Facts** 

#### **Active ingredient (in each tablet)**

Cetirizine HCl 10 mg

#### Purpose

Antihistamine

#### Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat

#### **Warnings**

**Do not use** if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.

**Ask a doctor before use if you have** liver or kidney disease. Your doctor should determine if you need a different dose.

**Ask a doctor or pharmacist before use if you are** taking tranquilizers or sedatives.

#### When using this product

- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

**Stop use and ask a doctor if** an allergic reaction to this product occurs. Seek medical help right away.

#### If pregnant or breast-feeding

- if breast-feeding: not recommended
- if pregnant: ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

#### **Directions**

addite and children 6 Vears and	one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours. A 5 mg product may
OTION	one to hig tablet in 24 hours. A 3 hig product may

over	be appropriate for less severe symptoms.
adults 65 years and over	ask a doctor
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

#### Other information

- store between 20° to 25°C (68° to 77°F)
- do not use if clamshell is opened, or if foil inner seal imprinted with "ZYRTEC®" is broken or missing
- meets USP Dissolution Test 2

#### **Inactive ingredients**

colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide

#### Questions?

call **1-800-343-7805** (toll-free) or **215-273-8755** (collect)

#### PRINCIPAL DISPLAY PANEL

Original Prescription Strength

NDC 50580-726-36

 $ZYRTEC^{\circledR}$ 

**ALLERGY** 

Cetirizine HCl tablets

10 mg /antihistamine

Indoor & Outdoor Allergies

24

hour

#### Relief of

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

30 Tablets

10 mg each

(Actual Size)

### Original Prescription Strength NDC 50580-726-36 ALLERGY Cetirizine HCl tablets 10 mg /antihistamine Indoor & Outdoor Allergies Relief of Sneezing hour • Runny Nose Itchy, Watery Eyes Itchy Throat or Nose **30** Tablets 10 mg each (Actual Size) Important: Read all product information before using. Keep this card for important information. Drug Facts Drug Facts (continued)

# Drug Facts Drug Facts Drug Facts (continued) Other information ■ store between 20° to 25°C (68° to 77°F) ■ do not use if clamshell is opened or if foil inner seal imprinted with "ZYRTEC®" is broken or missing ■ meets USP Dissolution Test 2 Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide

Warnings

Questions? call 1-800-343-7805 (toll-free) or 215-273-8755 (collect)

DO NOT USE IT you have ever had an amergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.

#### When using this product

- drowsiness may occur avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and aska doctor if an allergic reaction to this product occurs. Seek medical help right away.

#### If pregnant or breast-feeding:

- if breast-feeding: not recommended
- if pregnant: ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions	
adults and children 6 years and over	one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours. A 5 mg product may be appropriate for less severe symptoms.
adults 65 years and over	ask a doctor
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor



The trade dress of this ZYRTEO® package is subject to trademark protection.

Active ingredient made in Switzerland

Distributed by:

JOHNSON & JOHNSON CONSUMER INC.

McNeil Consumer Healthcare Division Fort Washington, PA 19034 USA SJ&JCI 2017 www.zyrlec.com USD 601,012; USD 606,856; USD 620,359; US 7,866,475

30040818







#### ZYRTEC ALLERGY

cetirizine hydrochloride tablet, film coated

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-726		
Route of Administration	ORAL				

## Active Ingredient/Active Moiety Ingredient Name Basis of Strength Cetirizine Hydrochloride (UNII: 640047KTOA) (Cetirizine - UNII:YO7261ME24) Cetirizine Hydrochloride 10 mg

Inactive Ingredients				
Ingredient Name	Strength			
Silicon Dioxide (UNII: ETJ7Z6XBU4)				
Croscarmellose Sodium (UNII: M28 OL 1HH48)				
Hypromellose, Unspecified (UNII: 3NXW29V3WO)				
Lactose Monohydrate (UNII: EWQ57Q8I5X)				
Magnesium Stearate (UNII: 70097M6I30)				
Microcrystalline Cellulose (UNII: OP1R32D61U)				

Polyethylene Glycol, Unspecified (UNII: 3WJQ0SDW1A)	
Titanium Dioxide (UNII: 15FIX9 V2JP)	

Product Characteristics				
Color	WHITE	Score	2 pieces	
Shape	RECTANGLE (rounded-off rectangular biconvex tablet)	Size	9 mm	
Flavor		Imprint Code	ZYRTEC;10;MG	
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-726- 03	50 in 1 CARTON	01/01/2008	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50580-726- 13	3 in 1 CARTON	03/21/2009	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:50580-726- 30	5 in 1 PACKAGE	01/01/2008	
3		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:50580-726- 32	14 in 1 PACKAGE	01/01/2008	
4		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:50580-726- 36	1 in 1 PACKAGE	0 1/0 1/20 0 8	
5		30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
6	NDC:50580-726- 50	1 in 1 PACKAGE	01/26/2010	
6		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
7	NDC:50580-726- 51	2 in 1 PACKAGE	01/26/2010	
7		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
8	NDC:50580-726- 38	1 in 1 PACKAGE	0 1/0 1/20 0 8	
8		45 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
9	NDC:50580-726- 70	1 in 1 PACKAGE	01/01/2008	
9		70 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
10	NDC:50580-726- 90	2 in 1 PACKAGE	01/26/2010	
10		45 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
11	NDC:50580-726- 66	75 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	01/01/2008	
12	NDC:50580-726- 40	1 in 1 PACKAGE	0 1/20 /20 14	
12		40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
13	NDC:50580-726- 91	2500 in 1 CARTON	07/27/2018	
13		1 in 1 POUCH; Type 0: Not a Combination Product		
14	NDC:50580-726- 92	50 in 1 TRAY	07/12/2018	

14		1 in 1 POUCH; Type 0: Not a Combination Product	
15	NDC:50580-726- 93	3 in 1 CARTON	07/27/2018
15		1 in 1 POUCH; Type 0: Not a Combination Product	
16	NDC:50580-726- 94	1 in 1 PACKAGE	06/15/2020
16		60 in 1 BOTTLE; Type 0: Not a Combination Product	
17	NDC:50580-726- 95	1 in 1 PACKAGE	06/15/2020
17		90 in 1 BOTTLE; Type 0: Not a Combination Product	
18	NDC:50580-726- 96	5 in 1 CARTON	05/30/2020
18		1 in 1 POUCH; Type 0: Not a Combination Product	
19	NDC:50580-726- 97	14 in 1 CARTON	05/30/2020
19		1 in 1 POUCH; Type 0: Not a Combination Product	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA0 19835	0 1/0 1/20 0 8	

Labeler - Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division (878046358)

Revised: 7/2020 Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division